United States District Court

EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
	§	
v.	§	CASE NO. 4:16-CV-350
	§	Judge Mazzant
PROPEL ORTHODONTICS, LLC	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is OrthoAccel's Motion for Preliminary Injunction and Permanent Injunction (Dkt. #57). Based on the pleadings, the numerous briefs and submissions, the arguments and evidence presented at a hearing on the motion, and the applicable law, the Court enters the findings of fact and conclusions of law set forth below. Based on these findings and conclusions, the Court **GRANTS** OrthoAccel's Motion for Preliminary Injunction.

BACKGROUND

Plaintiff, OrthoAccel Technologies, Inc. ("OrthoAccel"), is a medical device company that manufactures dental appliances. In 2008, OrthoAccel developed a prototype hands-free dental device that uses gentle vibrations to accelerate tooth movement when used with orthodontic treatment. This prototype would eventually become the AcceleDent device, which has two main functional components: (1) a "Mouthpiece" and (2) an "Activator." The Activator is a small extraoral component that generates a vibrational force of 0.25N at 30 Hz. The Activator connects directly to the Mouthpiece, which the patient lightly bites down on for 20 minutes daily to accelerate tooth movement during orthodontic treatment.

On November 5, 2011, the Food and Drug Administration ("FDA") granted 510(k) clearance for AcceleDent as "an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps

facilitate minor anterior tooth movement." A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective as a legally marketed device (a "predicate device") that is not subject to premarket approval. 510(k) clearance is required for Class II devices, but Class I devices are 510(k) exempt. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as a Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Dental implants and braces are examples of Class II devices.

In 2012, OrthoAccel launched its Class II AcceleDent device in the United States to be used in conjunction with orthodontic treatment. In 2013, OrthoAccel launched the AcceleDent Aura ("Aura"), the second generation of AcceleDent, which initially was cleared to be used with braces only. On July 8, 2016, the Aura was cleared for use with clear aligners. Orthodontic patients wear a series of these removable aligners, marketed under names such as Invisalign and ClearCorrect, to gradually straighten their teeth.

Defendant Propel Orthodontics, LLC ("Propel") is also a medical device company that manufactures dental appliances. In January 2016, Propel began marketing a vibratory Class I device designed to help seat clear aligners. In March 2016, Propel released the VPro5, which operates at 120 Hz and requires five minutes of daily use to properly seat (i.e., fit better on the teeth) clear aligners. The VPro5 costs significantly less than the OrthoAccel Aura.

Propel primarily markets the VPro5 through its sales force in a consultative setting. Propel sales representatives promote the VPro5 by telling orthodontists that the device offers several clinical benefits ("5 Clinical Benefits"). These 5 Clinical Benefits include: (1) more efficient aligner seating, (2) relieves orthodontic pain, (3) accelerates tooth movement, (4) fast

tracks retention, and (5) stimulates bone growth and remodeling. Propel's sales force markets the VPro5 as a quicker, cheaper alternative to the AcceleDent device.

On July 19, 2016, OrthoAccel filed its Motion for Preliminary Injunction and Permanent Injunction (Dkt. #57), seeking injunctive relief from Propel's alleged false advertising under the Lanham Act. On August 30, 2016, Propel filed its response (Dkt. #73). On September 9, 2016, OrthoAccel filed its reply (Dkts. #95, #96). On September 19, 2016, Propel filed its sur-reply (Dkt. #109). The Court held oral argument at the request of the parties on September 20, 2016. The hearing continued on October 3, 2016, and concluded on October 4, 2016.[1]

LEGAL STANDARD

To obtain a preliminary injunction, it is well established that a movant must show: (1) a substantial likelihood that the movant will ultimately prevail on the merits; (2) a substantial threat that the movant will suffer irreparable injury if the injunction is not granted; (3) that the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) that granting the injunction will not disserve the public interest. *Paulsson Geophysical Servs., Inc. v. Sigmar*, 529 F.3d 303, 309 (5th Cir. 2008); *Speaks v. Kruse*, 445 F.3d 396, 399–400 (5th Cir. 2006); *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985) (citing *Canal Authority of State of Fla. v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974)).

The decision to grant or deny a preliminary injunction is left to the sound discretion of the district court. *Miss. Power & Light*, 760 F.2d at 621. A preliminary injunction is an extraordinary remedy which should only be granted if the movant has clearly carried his burden

[1] On October 14, 2016, OrthoAccel filed a Post-Hearing Brief (Dkt. #126).On October 17, 2016, Propel filed a Motion to Strike the brief (Dkt. #130). On October 21, 2016, OrthoAccel filed its Response in Opposition (Dkt. #141). The Court did not consider the Post-Hearing Brief and will issue a separate order striking the brief.

of persuasion on all four factors. *Id.*; *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (A preliminary injunction is a "drastic remedy" that "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion.") (citation omitted) (emphasis in original); *PCI Trans., Inc. v. Fort Worth & W. RR Co.*, 418 F.3d 535, 546 (5th Cir. 2005) ("[t]he plaintiff has the burden of introducing sufficient evidence to justify the grant of a preliminary injunction."). As a result, "[t]he decision to grant a preliminary injunction is to be treated as the exception rather than the rule." *Miss. Power & Light*, 760 F.2d at 621; *House the Homeless, Inc. v. Widnall*, 94 F.3d 176, 180 (5th Cir. 1996).

ANALYSIS

In a typical preliminary injunction application, the *movant* must clearly meet its burden of persuasion on all four requirements for the Court to grant injunctive relief. *See Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). OrthoAccel, the movant, argues that the burden should shift to Propel under the *Novartis* exception. *See Novartis v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578 (3d Cir. 2002). In *Novartis*, a pharmaceutical company marketed an antacid as "night time strength" without arguing or presenting *any evidence* that the drug was specifically formulated for night time heartburn or that its product actually remedied heartburn at night more effectively than heartburn during the day. *Id.* at 590. The Fifth Circuit noted that it had previously specifically declined to answer "whether *completely unsubstantiated* advertising claims violate the Lanham Act absent proof that consumers are actually misled by this lack of substantiation." *Id.* at 589 (emphasis in original). But the Fifth Circuit decided to answer what it had previously left open and held, "although the plaintiff normally has the burden to demonstrate that the defendant's advertising claim is false, a court may find that a completely

unsubstantiated advertising claim by the defendant is *per se* false without additional evidence from the plaintiff to that effect." *Id.* at 590.

OrthoAccel argues that the Court should apply the *Novartis* exception, but the Fifth Circuit has not adopted the *Novartis* exception. And the *Novartis* exception would not apply regardless because Propel's claims are not *completely unsubstantiated*. *See id.* at 589–90. The Court finds the *Novartis* exception inapplicable because Propel has offered some evidence substantiating its advertising claims. Thus the burden of proof remains with OrthoAccel to show that the advertising is false and misleading.

Substantial Likelihood of Success on the Merits

In order for the Court to grant injunctive relief, OrthoAccel must show a substantial likelihood that it will ultimately prevail on the merits. *See Sigmar*, 529 F.3d at 309. OrthoAccel alleges that Propel engaged in deceptive advertising in violation of the Lanham Act and Texas common law. In the Fifth Circuit, the elements of a false advertising claim under the Lanham Act are: (1) the defendant made a false statement of fact about its product in a commercial advertisement; (2) the statement actually deceived or had a tendency to deceive a substantial segment of its audience; (3) the deception was material or likely to influence the purchasing decision; (4) the defendant caused the false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result. *Logan v. Burgers Ozark Country Cured Hams, Inc.*, 263 F.3d 447, 462 (5th Cir. 2001); 15 U.S.C. § 1125. The Court will discuss each element in turn.

Falsity

In order to show a substantial likelihood of success on the merits, OrthoAccel must identify a false statement of fact actionable under the Lanham Act. Because per se falsity is not triggered under the *Novartis* exception, OrthoAccel carries the burden of proving falsity.

The Fifth Circuit distinguishes literally false statements from misleading statements. *See Pizza Hut, Inc. v. Papa John's Intern., Inc.*, 227 F.3d 489 (5th Cir. 2000). In the Fifth Circuit, materiality is presumed for literally false statements. *Id.* There are several claims made by Propel that are literally false. OrthoAccel first identifies "Vibration Objections and Answers," an internal Propel document created for a presentation given to its sales force. (PX 2). Propel's CEO, Bryce Way, testified that the presentation was designed to stimulate and educate the sales force so the representatives could sell the VPro5. The first question asks, "What clinical research do you have that your vibration works?" The proposed answer reads, "We have many research studies that show the benefits of high frequency vibration. Let me detail some of them with you." A similar claim appears in the March 2016 launch presentation, which states that there are "significant clinical findings that support the VPro5's ability to increase bone formation and accelerate tooth movement." (PX 3). But no such studies existed. The claim that Propel had "many studies" to support its claims is literally false because at the time the sales force engaged the marketplace, there were no clinical findings or studies supporting the notion that the VPro5 could provide its 5 Clinical Benefits. Another literally false statement appears in the same document, which states the VPro5's 120 Hz is the "optimal frequency" for achieving the 5 Clinical Benefits. (PX 2). This claim is completely unsubstantiated and literally false. *See Kinetic Concepts, Inc. v. Bluesky Med. Group, Inc.*, SA-03-CA-0832-RF, 2005 WL 3068223, at *4 (W.D. Tex. Nov. 1, 2005) ("Unsubstantiated comparison claims made in an advertisement have

been found *per se* false.") None of the studies relied upon by Propel tested the 120 Hz frequency or otherwise concluded that the frequency was optimal for accelerated tooth movement.

The final literally false statement identified by OrthoAccel appeared in a Propel advertisement that claimed a "prototype of the VPro5 device" was used in the Dr. M. Alikhani studies. (PX 6). Propel later corrected this advertisement and claims fewer than twenty dentists saw the false statement, but the statement was literally false when disseminated. (DX 17).

In addition to proving falsity from these literally false statements, OrthoAccel meets its burden in proving falsity by showing the literature does not support the claims. OrthoAccel asserts that in order to actually scientifically disprove Propel's claims, it would need to conduct two to three years of blind studies using the VPro5. But when a "defendant's promotion implicitly or explicitly refers to tests or data, a plaintiff can satisfy its burden of proving that the promotion is literally false by demonstrating that the tests are not sufficiently reliable to permit a person to conclude with reasonable certainty that they established the claim made." *Pamlab, LLC v. Macoven Pharm., LLC*, 881 F. Supp. 2d 470, 467 (S.D.N.Y. 2012); *see Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230 (5th Cir. 2014) (finding falsity where plaintiff established that competitors' tests were not scientifically reliable). Thus, OrthoAccel can meet its burden as to falsity by showing that Propel's studies, tests, and data do not support the advertising claims.

The first study relied upon by Propel is Dr. Alikhani's high frequency study. (PX19). Dr. Alikhani studied high frequency vibration as a therapeutic tool to preserve bone following tooth extractions. The study did not involve the VPro5 or any prototype thereof. The study also did not use clear aligners or involve orthodontic tooth movement in any capacity. Propel relies on a second Dr. Alikhani study—Osteogenic Effect of High-frequency Acceleration on Alveolar Bone. (PX 20). Similarly, this study does not involve a VPro5, orthodontic tooth movement, or

clear aligners. At oral argument, OrthoAccel's expert, Dr. Dubravko Pavlin, testified that Dr. Alikhani's studies do not support the notion that the VPro5 accelerates tooth movement or provides any of the 5 Clinical Benefits. More importantly, Dr. Alikahni himself stated he was "[s]ad this data are being misused" when he learned Propel was attempting to use his studies as support for their advertising claims. (PX 53).

Propel also relies upon Dr. Stefan Judex's article, which studied bone formation induced by applying high-frequency vibration to muscles in rat appendages. (PX 22). Dr. Judex did not study orthodontic tooth movement or utilize the VPro5, clear aligners, or a 120 Hz frequency. At oral argument, Dr. Pavlin conceded that this study was well conducted, but claimed there was no useful comparison to the VPro5. Dr. Judex's study does not provide a basis for supporting any of the advertised 5 Clinical Benefits.

Propel relies on another study, by Dr. Chidchanok Leethanakul, that measured the effect of a vibrating toothbrush placed on a single braces bracket for pain relief. (PX 21). Dr. Pavlin noted at oral argument that this is the only study relied upon by Propel that actually studies orthodontic tooth movement. Dr. Pavlin stated that since Dr. Leethanakul did not disclose the force applied by the toothbrush, a useful comparison to the VPro5 could not be made. Further, the study did not test clear aligners or utilize a device even similar to the VPro5. The study does not support the notion that the VPro5 is capable of providing the alleged 5 Clinical Benefits.

The final study relied on by Propel is the Dr. Payam Attai study, which compared aligner seating with a vibratory device versus aligner seating with a "chewie." (DX 27). A chewie is a small, cylindrical foam stick that patients bite down on to help seat aligners. Dr. Attai's "study" asked nine dental patients whether they were satisfied with the VPro5's ease of use in a post-treatment questionnaire. Based on this questionnaire, Dr. Attai concluded that the vibratory

device offered better aligner seating than a traditional chewie. This "study" did not address the 5 Clinical Benefits or otherwise support any of Propel's advertising claims.

The studies introduced by Propel do not support the VPro5's advertising claims. Propel attempts to offer various non-study publications as evidence of the VPro5's efficacy. OrthoAccel, Dr. Pavlin, and the Court agree that these articles do not support the notion that the VPro5 can offer the 5 Clinical Benefits identified, but the Court will address these articles in turn.

Propel offers Dr. Amit Lala's article as evidence of the VPro5's efficacy. (PX 24). Dr. Lala's article is not a study—it does not test high frequency vibration, its effects on orthodontic tooth movement, or offer any scientific support for the alleged benefits of the VPro5. Dr. Lala concludes, "It can be hypothesized that a vibration device operating in the high frequency range would likely be most effective in creating [orthodontic tooth movement] . . . ." This article only hypothesizes about the potential benefits orthodontic vibration therapy may provide, and does not address Propel's 5 Clinical Benefits. Further, Dr. Pavlin testified that the articles cited by Dr. Lala do not support his extrapolation. The Court finds that Dr. Lala's article does not support Propel's advertising claims.

Propel also offers Dr. Thomas Shipley's article as evidence of the VPro5's efficacy. (PX 23). Dr. Shipley's article summarizes a single patient's experience with the VPro5 device. Dr. Shipley claims that he is able to offer his patients more treatment predictability, less refinements, less discomfort, better patient compliance with a five-minute usage time, and greater patient satisfaction. While Dr. Shipley's article concludes that the VPro5 might offer some benefits based on a single-patient survey, it does not support the notion that the VPro5 can provide any of the 5 Clinical Benefits.

Propel claims that Dr. Gary Brigham's article supports the VPro5's marketing claims. (PX 25). Similar to Dr. Lala's article, Dr. Brigham's article is neither a study nor a test. Dr. Brigham states, "some preliminary research suggests that high-frequency vibratory devices may accelerate teeth movement." But Dr. Brigham did not test the VPro5 or conclude that it moved teeth faster, fast tracked retention, reduced pain, or stimulated bone growth and remodeling. Dr. Brigham himself stated, "Independent, randomized, controlled trials have not yet established the efficacy of these appliances." Further, Dr. Pavlin testified that the articles cited by Dr. Brigham do not support his extrapolation.

OrthoAccel has met its burden in proving that the tests and data are not sufficiently reliable to establish that the VPro5 can offer its advertised 5 Clinical Benefits. *See Pamlab, LLC*, 881 F. Supp. 2d at 467. The Court agrees with the line of cases that prevent a defendant from using irrelevant, unreliable studies to support its promotional claims. *See Eastman Chem. Co.*, 775 F.3d at 230; *SEB USA, Inc. v. Euro-Pro Operating, LLC*, 774 F.3d 192, 202 (3d Cir. 2014) (holding that a defendant's use of irrelevant studies to support promotional claims was insufficient). Thus OrthoAccel has met its burden in proving literal falsity. *See Pamlab, LLC*, 881 F. Supp. 2d at 467; *Eastman Chem. Co.*, 775 F.3d at 230.

Deception

Plaintiffs seeking injunctive relief must prove that defendant's representations "have a tendency to deceive customers." *Pizza Hut*, 227 F.3d at 489; *see Mission Pharmacal Co. v. Vitus Pharm., LLC*, 23 F. Supp. 3d 748, 759 (W.D. Tex. 2014) ("[P]laintiff must show that the statements have a tendency to deceive consumers by producing evidence that at least some consumers were confused." (citing *Pizza Hut, Inc.*, 227 F.3d at 497–98 (internal citations omitted)). To prove a tendency to deceive, a plaintiff "need not present consumer surveys or

testimony demonstrating actual deception." *Pizza Hut, Inc.*, 227 F.3d at 498; *but see Apple Inc. v. Amazon.com Inc.*, 915 F. Supp. 2d 1084, 1090 (N.D. Cal. 2013) ("If an advertisement is not false on its face, plaintiff asserting false advertising claim under Lanham Act must produce evidence, usually in the form of market research or consumer surveys, showing exactly what message was conveyed that was sufficient to constitute false advertising."). The Fifth Circuit assumes that literally false statements actually mislead consumers. *S&H Industries, Inc. v. Selander*, 932 F. Supp. 2d 754 (N.D. Tex. 2013) ("If the statements at issue are shown to be literally false, a court must assume that the statements actually misled consumers, without requiring any evidence of their impact on consumers." (citing *Logan*, 263 F.3d at 462; *Pizza Hut*, 227 F.3d at 497)). Because OrthoAccel has met its burden in proving literal falsity, the Court assumes the statements actually misled customers.

OrthoAccel has nonetheless proven actual deception by showing Propel's claims are misleading and have deceived the doctors and staff to whom Propel markets the VPro5. OrthoAccel provides captures of various dentists' websites that copy the alleged 5 Clinical Benefits of the VPro5 as proof that some consumers were confused. (PX 33). These websites show that Propel's advertising had a tendency to deceive consumers. As a more direct indicator of deception, OrthoAccel provides Dr. Mark K. Batesole's declaration. Dr. Batesole received a marketing email from a Propel sales representative announcing the launch of the VPro5. (PX 12). The email summarized some advantages of the VPro5 and compared its cost to the AcceleDent product. *Id.* Dr. Batesole stated he "understood that Propel was introducing a competing device [to] AcceleDent" and "would expect the VPro5 to have scientific support, similar to AcceleDent." (PX 54). This declaration proves actual deception, which is more than what is required for injunctive relief. *See Pizza Hut*, 227 F.3d at 497.

Materiality

The parties agree that the deception is material because the advertisements will likely influence the consumer's purchasing decision. And OrthoAccel does not need to introduce evidence of materiality. *See Pizza Hut*, 227 F.3d at 497 ("With respect to materiality, when the statements of fact at issue are shown to be literally false, the plaintiff need not introduce evidence on the issue of the impact the statements had on consumers."). The Court finds that Propel's false advertising is material.

Interstate Commerce

In order to show a substantial likelihood of success on the merits, OrthoAccel must prove that the advertising entered interstate commerce. *See Logan*, 263 F.3d at 462. Propel admits that it promotes and sells the VPro5 to doctors around the United States through its sales force (Dkt. #11). The Court finds that OrthoAccel has met its burden on proving this element. *See Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1384 (5th Cir. 1996) (finding that promotion to those specifically intended to buy the defendants' product was sufficient dissemination). The Court finds that Propel's advertising involved interstate commerce.

Injury

In order to prove substantial likelihood of success on the merits, OrthoAccel must prove it has suffered an injury. Michael Lowe, OrthoAccel's CEO, testified that OrthoAccel is losing market share to Propel as evidenced by a sharp decline in sales following the launch of the VPro5. (Dkt. #95-1). OrthoAccel has met this burden, which is discussed in depth in the following section.

Irreparable Injury

OrthoAccel must establish that it will face irreparable harm if the Court does not grant injunctive relief. It is well established that loss of market share due to false advertising constitutes irreparable harm. *See Novartis*, 290 F.3d at 596 ("In a competitive industry where consumers are brand loyal . . . loss of market share is a potential harm which cannot be redressed by a legal or an equitable remedy following a trial." (internal citations omitted)). In 38 out of 39 months before the VPro5 launch, OrthoAccel's monthly net U.S. revenues increased on a year-over-year basis. Michael Lowe testified that OrthoAccel's annual operating plan and actual revenues varied by 7% in 2014 and 2% in 2015. In 2016, from April to July, the variance measured 57% following the launch of the VPro5.

Propel only provided a 43-day period of sales data in July and August of 2016 to OrthoAccel for comparison. Over these 43 days, Propel's sales totaled $1.4 million and OrthoAccel's sales declined by over $300,000, to $1.1 million. This data supports that OrthoAccel is losing market share to Propel. Propel cites the *Mylan* case to support its argument that the Court should deny injunctive relief, asserting OrthoAccel is merely attempting to prevent legitimate competition from entering the marketplace. *See Mylan Inc. v. SmithKline Beecham Corp.*, No. CIV.A. 10-04809 JAP, 2010 WL 4181139, at *4 (D.N.J. Oct. 20, 2010) (holding that Plaintiff's claims of lost market share are merely complaints "about a harm that is a result of legitimate competition in the market."). But Propel is not legitimate competition. Propel disseminated false and misleading advertisements throughout its participation in the marketplace. The Court finds that OrthoAccel has met its burden in proving irreparable harm.[2]

[2] Further, courts in this circuit have held that under the Lanham Act, irreparable injury is presumed based on alleged comparative misrepresentations by a competitor. *See Greater Houston Trans. Co. v. Uber Tech., Inc.*, No. 4:14–cv–0941, 2015 WL 1034254, at *21 (S.D. Tex.

Weighing Equities

The Court understands that this decision will have a considerable impact on the livelihood of both companies. But the irreparable harm that OrthoAccel will suffer if the Court does not enjoin Propel from disseminating false advertising greatly outweighs Propel's likely loss in sales. Propel claims an injunction would restrain truthful speech. But the speech is not truthful and the harm to Propel is self-imposed. *See Novartis*, 129 F. Supp. 2d at 369 (finding that any financial loss suffered by defendant as a result of its false marketing is "self-imposed"); *W.L Gore & Assocs., Inc. v. Totes, Inc.*, 788 F. Supp. 800, 812 (finding that where false and misleading advertising claims are made, any "prejudice" which accrues to the defendant as a result is self-inflicted). The Court will not completely enjoin Propel from marketing its product. Propel can still claim that the VPro5 aids in aligner seating. It will only enjoin Propel from disseminating claims of the VPro5's 5 Clinical Benefits, which are false and misleading.

Public Interest

OrthoAccel claims that an injunction would serve the public interest by preventing Propel from marketing a medical device to doctors for use on patients without any clinical or scientific support for its claims. Propel argues that providing an alternative medical device serves the public interest. *See Cardiovascular Sys., Inc. v. Medtronic, Inc.*, No. C95-03577-DLJ, 2008 WL 4647384, at *1 (N.D. Cal. Oct. 20, 2008) (basing part of its denial of an injunction extension on the "public policy in terms of making the most medical devices available to the public"). But the public will not be deprived because Propel can still market the VPro5 to dentists as an aligner seater. And public policy favors preventing the dissemination of false and misleading advertising. *See Novartis*, 209 F.3d at 597; *Quantum Fitness Corp. v. Quantum Lifestyle Ctrs.*,

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Mar. 10, 2015). The Court agrees with the *Uber* court and finds that OrthoAccel will suffer irreparable injury if the Court does not grant injunctive relief.

LLC, 83 F. Supp. 2d 810, 832 (S.D. Tex. 1999) (finding "the public interest is always served by requiring compliance with Congressional statutes such as the Lanham Act."). The Court finds that the public is best served if Propel is enjoined from disseminating false information.

Unclean Hands

Propel claims that the doctrine of unclean hands bars OrthoAccel from seeking equitable relief. Propel forms this defense based on statements made by OrthoAccel that allegedly misrepresent Propel's FDA status. 21 C.F.R. § 807.97 ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."). But these arguments are preempted by the Food, Drug, and Cosmetic Act. *See Healthpoint, Ltd. v. Stratus Pharm., Inc.*, 273 F. Supp. 2d 769, 815–16 (W.D. Tex. 2001) (declining to exercise jurisdiction over FDA claims because "the proper approach is for the Court to defer to the FDA for the resolution of issues within its primary jurisdiction and to exercise jurisdiction over Lanham Act and other claims which do not require application or construction of FDA law, regulations, or policy."). Even if the argument were not preempted, Propel does not show by clear and convincing evidence that OrthoAccel's conduct "shock[s] the moral sensibilities of the judge, or . . . was offensive to the dictates of natural justice." *iFLY Holdings LLC v. Indoor Skydiving Germany Gmbh*, No. 2:14-CV-1080-JRG-RSP, 2016 WL 3675136, at *1 (E.D. Tex. Mar. 25, 2016).

CONCLUSION

The Court set out its conclusions of law throughout its above discussion of the case, but it repeats them here for the sake of clarity:

- There is a substantial likelihood of success on the merits of OrthoAccel's false advertising claim under the Lanham Act

- There is a substantial threat of irreparable injury to OrthoAccel without adequate legal remedy if the injunction does not issue.
- OrthoAccel's threatened injury if the court were to deny the injunction outweighs the harm to Propel should the injunction issue.
- The injunction will not disserve the public interest.

It is therefore **ORDERED** that OrthoAccel's Application for a Preliminary Injunction is hereby **GRANTED**.

It is further **ORDERED** that Propel and all persons acting on its behalf, in concert with it or under its control, is enjoined from engaging in the following activities:

Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial matter, that the:

- VPro5 accelerates tooth movement;
- VPro5 stimulates bone growth and tooth remodeling;
- VPro5 fast tracks, or otherwise aids retention;
- VPro5 relieves pain or discomfort;
- VPro5's higher frequency works better than AcceleDent's lower frequency
- VPro5 is effective to accelerate tooth movement, stimulate bone growth and tooth remodeling, aids retention or relieves pain in less time than AcceleDent.

It is further **ORDERED** that unless terminated earlier, this preliminary injunction shall expire upon the issuance of a final decision by the Court in this case.

It is further **ORDERED** that this preliminary injunction shall not be effective unless and until Plaintiff has filed an appropriate bond or cash deposit in lieu thereof in the amount of $10,000.

SIGNED this 26th day of October, 2016.

AMOS L. MAZZANT
UNITED STATES DISTRICT JUDGE